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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|---------------------|------------------|
| 10/690,685 | 10/22/2003 | Shigeru Nemoto | KIT02.001DV2 | 6145 |
| 20995 | 7590 | 02/08/2006 | EXAMINER | |
| KNOBBE MARTENS OLSON & BEAR LLP | | | HUH, BENJAMIN | |
| 2040 MAIN STREET | | | ART UNIT | |
| FOURTEENTH FLOOR | | | PAPER NUMBER | |
| IRVINE, CA 92614 | | | 3767 | |

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/690,685

Applicant(s)

NEMOTO, SHIGERU

Examiner

Benjamin Huh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/22/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/26/2004 & 9/9/20.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements (IDS) received on 09/09/2005 & 01/26/2004 are acknowledged. The IDS meets the requirements of 37 CFR 1.97 & 1.98 and therefore references listed therein have been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Botich et al (US Patent No. 5188599). Botich et al discloses a retractable needle system as seen in figures 1-6 comprising a syringe barrel 55 with a flange 79 having a projection 83 on a rear surface thereof, also see col. 9 lines 41-50; the flange being inherently capable to be held by a flange insertion groove so as to fix the syringe barrel; the projection 83 being formed and being inherently capable to be inserted into a flange insertion groove on a cylinder holder and mounted in a use position; and a tip of the projection 83 being inherently capable of being compressed whereby the flange fully capable of being fitted and fixed into a flange insertion groove due to the size and shape of the flange not

severely differing from the normal sizes and shapes of a syringe flange, and due to its ability to perform in the environment.

With regards to claim 2, the projection 83 and the flange 79 together are inherently capable of being inserted into a flange insertion groove and the tip of the projection 83 is capable of being compressed so as to press the flange against a front sidewall surface of the flange insertion groove in a use position due to the size and shape and ability to perform in the environment.

With regards to claim 3, the projection 83 has a narrower width toward the tip as can be seen in figure 1.

With regards to claim 4, the flange has a two flange cut portions symmetrically positioned in the flange opposite to each other seen in figures 1-3.

With regards to claim 5, the flange has an even number of projections 83 symmetrically disposed to one another on the flange over a portion of the flange where the two flange cut portions are not provided as can be seen in figure 1 where there is a total of 6 projections with an even amount on each side of the flange.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Spallek et al (US Patent No. 5897532). Spallek discloses a cylinder holder 1 seen in figures 1-4 comprising a flange insertion groove for holding a syringe barrel; a projection 3 & 6 on an inner wall surface of the flange insertion groove to be contacted with a rear surface of a flange of the syringe barrel; the projection 3 & 6 being so formed that when the flange is inserted in the flange insertion groove and mounted in a use position, the

projection 3 & 6 compresses the flange, thereby the flange is fitted and fixed in the flange insertion groove. The finger grip is inherently capable of holding a syringe barrel as well as fitting and fixing the flange of the syringe barrel in the flange insertion groove due to its shape, size, and ability to work in the necessary environment.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al (US Patent No. 4540405). Miller et al discloses an injection system comprising a cylinder holder 2 comprising a flange insertion groove seen in figures 1-2 for holding a syringe barrel 42; and a projection 34 on an inner surface of the flange insertion groove to be contacted with a rear surface of a flange 48 of the syringe barrel; the projection 34 being so formed when the flange is inserted in the flange insertion groove and mounted in a use position the projection 34 compresses the flange 48, thereby, the flange is fitted and fixed in the flange insertion groove as can be seen in figure 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (US Patent No. 4540405). Miller et al discloses an injection system comprising a cylinder holder 2 comprising a flange insertion groove seen in figures 1-2 for holding a syringe barrel 42; and a projection 34 on an inner surface of the flange insertion groove to be contacted with a rear surface of a flange 48 of the syringe barrel; the projection 34 being so formed when the flange is inserted in the flange insertion groove and mounted in a use position the projection 34 compresses the flange 48, thereby, the flange is fitted and fixed in the flange insertion groove as can be seen in figure 2. The injection system also comprises a syringe barrel comprising a flange 48 to be held by the flange insertion groove seen in figures 1 & 2. Even though Miller does not disclose a syringe barrel comprising a concave portion formed on the rear surface of the flange attention is directed to Stanners (US Patent No. 5593391). The Stanners reference discloses a syringe barrel comprising a concave portion formed on the surface of the flange in figures 3 & 15 and it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate a concave portion to the surface of the flange of Miller in order to allow a more secure grip of the projections to the syringe barrel to prevent movement of the syringe barrel.

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al (US Patent No. 5188599). Botich et al discloses an injection system comprising a syringe barrel comprising a flange having a projection being inherently capable of being inserted into a flange insertion groove. Even though the Botich system

does not explicitly state the projection to have a pyramid-like shape or a conical shape it would be obvious to one of ordinary skill in the art at the time of the invention to have a pyramid-like shape or conical shape or any other desired shape since applicant does not state the advantages of such shapes and therefore the projections seen in Botich are seen to have an equivalent function, way, and result as the pyramid or conical shape, attention is also directed to MPEP 2144 Section IV B, In Re Dailey for obvious design choice in shape.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al (US Patent No. 5188599) in view of Bitdinger et al (US Patent No. 5667495). Botich et al discloses an injection system comprising a syringe barrel comprising a flange having a projection being inherently capable of being inserted into a flange insertion groove. Even though Botich does not disclose a cylinder holder comprising a flange insertion groove for holding the syringe barrel and a concave portion formed on an inner wall surface of the flange insertion groove to be contacted with the rear surface of the flange of the syringe barrel; whereby, the concave portion is engaged with the projection on the rear surface of the flange when the syringe barrel is mounted in a use position attention is directed to Bitdinger. The Bitdinger reference discloses a cylinder holder 10 in figures 1-20 comprising a flange insertion groove 31 for holding the syringe barrel, and a concave portion (see col 4. line 60 – col 5. line 7) formed on an inner wall surface of the flange insertion groove to be contacted with the rear surface of the flange of the syringe barrel; whereby, the concave portion is inherently capable of engaging the

projection on the rear surface of the flange when the syringe barrel is mounted in a use position due to the size, shape, and ability to work in the environment.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al (US Patent No. 5188599) in view of Ritz (US Patent No. 3438549) or Tompkins (US Patent No. 4030498). Even though Botich does not disclose a pre-filled syringe attention is directed to Ritz or Tompkins. The Ritz and Tompkins references both disclose pre-filled syringes and it would be obvious to one of ordinary skill in the art at the time of the invention to have the syringe to be pre-filled for ease of use and to save time also attention is directed to Tompkins col 1. lines 15-17 where it states that "... many syringes are pre-filled ...".

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Burke (US Patent No. 6457606) discloses a cylinder holder seen in figures 1-3 for accepting a syringe barrel. Miller et al (US Patent No. 4540405) also discloses a cylinder holder as seen in figures 1 & 2. Gagnieux et al (US Publication No. 2003/0050607A1) discloses a syringe barrel with projections and a cylinder holder for the syringe barrel in figures 1-10. Vetter et al (US Patent No. 6296625) discloses a cylinder holder with a projection on an inner wall surface of the flange insertion groove as can be seen in figures 1-5. Bitdinger et al (US Patent No. 5667495) also discloses

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the cylinder holder to have projections in the flange insertion groove (see col. 6 line 47 – col 7. line 10).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BHH

BHH



MICHAEL J. HAYES
PRIMARY EXAMINER